UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

PATRICK RADDEN KEEFE	:	
Plaintiff,	:	
- v. -	:	1:19-cv-6752
U.S. FOOD & DRUG ADMINISTRATION,	:	
Defendant.	:	

COMPLAINT

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), to order the production of U.S. Food & Drug Administration ("FDA") records concerning the approval of Purdue Pharma's opioid painkiller OxyContin. Defendant FDA has withheld these records despite a properly filed FOIA request.

PARTIES

2. Defendant FDA is an agency of the United States with possession and control of the records sought by Plaintiff.
3. Plaintiff Patrick Radden Keefe is a National Magazine Award winning investigative journalist and author, currently working on a book about the opioid epidemic for Doubleday.
4. Keefe is the recipient of a Guggenheim Fellowship and fellowships at the Woodrow Wilson International Center for Scholars, the New America Foundation, and the Cullman Center for Scholars and Writers at the New York Public Library.

JURISDICTION AND VENUE

5. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

6. Keefe's residence and principal place of business are in the Southern District of New York and therefore venue is appropriate under 5 U.S.C. § 552(a)(4)(B).

FACTS

Background of FOIA Request

7. In 1995, the FDA approved the powerful extended-release opioid painkiller OxyContin, produced by Purdue Pharma ("Purdue"). In the ensuing years, hundreds of thousands of Americans have died from abuse of OxyContin and other opioids.

8. In 2007, Purdue pled guilty to federal criminal charges of misbranding OxyContin to downplay the risk of addiction and abuse.

9. In 2010, the FDA approved a reformulated version of OxyContin.

10. Over the past decade, the epidemic of opioid addiction has only grown. Purdue is currently a defendant in over a thousand lawsuits, many of them brought by state and local authorities. The discovery process in these cases has already brought to light many troubling internal documents from both the FDA and Purdue Pharma relating to the drug's approval process.

11. Insight into the FDA's approval process is critical to understanding the origins of the opioid crisis and whether the FDA failed to protect Americans from a dangerous drug.

FOIA Request and Constructive Denial

12. On May 10, 2019, Plaintiff submitted a FOIA request to the FDA for documents relating to the approval process for OxyContin (the "Request"). (Exhibit A)

13. The Request was acknowledged by the FDA and assigned tracking number 2019-4041.

14. The FDA has failed to provide - or formally deny - documents within twenty working days, and therefore has constructively denied the Request under 5 U.S. Code § 552(a)(6)(A)(ii).

CAUSE OF ACTION

Violation of the Freedom of Information Act for Wrongful Withholding of Agency Records

15. Plaintiff repeats and realleges paragraphs 1-14.

16. Defendant FDA has wrongfully withheld agency records requested by Plaintiff.

17. Plaintiff has exhausted all administrative remedies.

REQUESTED RELIEF

WHEREFORE, Plaintiff requests this Court:

(A) Order defendant to provide access to the requested documents in their entirety;

(B) Expedite this proceeding as provided for in 28 U.S.C. § 1657;

(C) Award Plaintiff costs and reasonable attorney fees in this action, as provided in 5 U.S.C. § 552(a)(4)(E); and

(D) Grant such other and further relief as may deem just and proper.

Dated: July 19, 2019

By: Dan Novack

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Pro Bono Counsel for Plaintiff